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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
A. James Mixson

Serial No. 10/018,103

Filing Date: November 5, 2001

For: HISTIDINE COPOLYMER AND METHODS FOR USING SAME

Group Art Unit: 1632

Examiner: Nguyen, Dave Trong

Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO OFFICE ACTION

In the Office Action dated October 1, 2003, the Examiner alleges that the patent application contains the following inventions or groups of inventions:

Group I: Claims 1-26, drawn to a pharmaceutical agent delivery composition comprising a linear peptide, with a proviso as set forth in claim 1 or claim 25.

Group II: Claims 1-26, drawn to a pharmaceutical agent delivery composition comprising a branched peptide, with a proviso as set forth in claim 1 or claim 25.

The Examiner stated that the inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. The Examiner has alleged that:

> Groups I and II are drawn to multiple distinct peptide-containing pharmaceutical composition and The claimed invention of Groups I-and II recite distinct materials and/or method steps that are neither required nor recited in the respective group, and thus have their own special technical features, e.g., **linear peptide vs. branched peptide**.
>
> Each invention is directed to distinct structure necessary to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I to II do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule

13.2, they lack the same or corresponding special technical features for the reasons set forth above.

Applicants provisionally elect the invention of Group II, Claims 1-26, drawn to a pharmaceutical agent delivery composition comprising a branched peptide, with a proviso as set forth in claim 1 or claim 25, with traverse. Applicants respectfully traverse the Examiner's restriction requirement on the grounds that the above groups represent a single general inventive concept and, therefore, possess the necessary unity of invention.

Pursuant to PCT Rule 13.1, an application shall relate to one invention, or a group of inventions "so linked as to form a single general inventive concept." See PCT Rule 13.1, MPEP Appendix T at T-48 (Aug. 2001); 37 CFR 1.475 and MPEP 1850. This is the "requirement of unity of invention." PCT Rule 13.2 states that the requirement of unity is fulfilled "only when the there is a technical relationship among those inventions involving one or more of the same or corresponding technical features." See PCT Rule 13.2, MPEP Appendix T at T-48; 37 CFR 1.475 and MPEP 1850. "Special technical features" means those features that "define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." Id (emphasis added).

Applicants traverse the objection based on unity of invention on the grounds that the restriction requirement has prematurely considered the special technical feature of the invention too narrowly. Applicant notes that a special technical feature common to both Groups I and II, i.e., a feature which defines the claimed invention as a whole over the prior art, is the use of a transport polymer comprising a peptide having at least 10 amino acid residues of which at least 10% of the amino acid residues are histidine, in a pharmaceutical agent delivery system. Based on the above statement by the Examiner, applicant believes that the Examiner has already taken the position that the molecular structure of the peptide is necessary to distinguish the claimed pharmaceutical agent delivery systems of Group I and II over the prior art. Applicants acknowledge that the peptides called for in the claims are further defined as having a molecular structure selected from a Markush group consisting of linear and branched (with certain provisos). Recitation of a Markush group; however, does not necessarily indicate more than one invention. Unity of invention of a Markush group under PCT Rule 13.2 is met when the alternatives of the Markush group are of a similar nature. See MPEP §1850, subsection D. MPEP §1850, subsection D further states:

> When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:
>
> (A) All alternatives have a common property or activity; and
>
> (B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or
>
> (C)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.
>
> In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, *or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art.* The structural element may be a single component or a combination of individual components linked together.

(Emphasis added). In the present case, the Grouped inventions I and II above share a common utility, the delivery of pharmaceutical agents to the interior of cells. See application at page 1, lines 8-10. Furthermore, the Grouped inventions I and II share a significant structural element which constitutes a structurally distinctive portion in view of existing prior art, (i.e., at least 10 amino acid residues of which at least 10% of the amino acid residues are histidine). The Examiner states that with respect to Groups I and II, "Each invention is directed to distinct structure necessary to achieve its respective and intended objective." It is not clear what scientific basis the Examiner is relying upon to reach this conclusion. It is the applicant's opinion that in the currently claimed invention it is the presence of histidine and minimum size of the peptide, and not the molecular structure of the peptide (i.e., linear or branched), that are factors important to achieving its respective and intended objective and that define the invention over the prior art. See application at page 26, lines 1-6 and page 27, lines 18-30. Because the Grouped inventions I and II have a common property or activity and a common structure, they must be regarded as being of a similar nature. Furthermore, since PCT Rule 13.2 is met when the alternatives of the Markush group are of a similar nature, Groups I and II meet the requirement of unity of invention. Accordingly, applicant respectively requests withdraw of the restriction requirement.

In the Office Action dated October 1, 2003, the Examiner further alleges that the patent application contains claims to more than one species of the generic invention that

lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The alleged species are as follows:

(a) A specifically named species of SEQ ID NO. as set forth in claim 3 or claim 14.

(b) A specifically named species of a chemotherapeutic agent or a particular combination of agents as listed in claim 8-10, and 19-21.

With respect to (a), should no generic claim be held allowable, applicant elects the species of SEQ ID NO. 5 as set forth in claim 3 or claim 14, which is read on by claims 1-26. With respect to (b), should no generic claim be held allowable, applicant elects the RNA-cleaving DNA oligonucleotide, which is read on by claims 1-26.

Accordingly, for all the above reasons, Applicants respectfully traverse the Examiner's restriction requirement. No fees are believed to be due in connection with this Response.

Respectfully submitted,
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